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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,953	04/26/2007	Beverly L. Wolgast	098817-0642	1700

99951 7590 01/27/2011  
Foley & Lardner LLP  
975 Page Mill Road  
Palo Alto, CA 94304

EXAMINER
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COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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01/27/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,953	<b>Applicant(s)</b> WOLGAST ET AL.	
	<b>Examiner</b> Brenda L. Coleman	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 58 and 62-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58 and 62-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/17/2010</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 58 and 62-90 are pending in the application.

This action is in response to applicant's amendments dated November 17, 2010.

Claims 1-57 and 59-61 have been canceled and claims 66-90 are newly added.

### *Response to Amendment*

Applicant's amendments and arguments filed November 17, 2010 have been fully considered with the following elect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 3) in the last office action, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 4a), b) and c) in the last office action, which are hereby **withdrawn**.
3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 5) in the last office action, which is hereby **withdrawn**.
4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 6) in the last office action, which is hereby **withdrawn**.

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5. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection labeled paragraph 7) in the last office action, which is hereby **withdrawn**.

6. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection labeled paragraph 8) in the last office action, which is hereby **withdrawn**.

7. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection labeled paragraph 9) in the last office action, which is hereby **withdrawn**.

8. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection labeled paragraph 10) in the last office action, which is hereby **withdrawn**.

9. The applicants' amendments and arguments are sufficient to overcome the obviousness-type double patenting rejection labeled paragraph 11) in the last office action, which is hereby **withdrawn**.

10. With regards to the provisional obviousness-type double patenting rejection of claims 54, 55, 58 and 60-65 over copending Application No. 11/793,473 labeled paragraph 12) in the last office action, the applicants' stated that when the only rejection remaining in the earlier filed of the two pending applications, the examiner should withdraw that rejection and permit the earlier filed application to issue as a patent

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without a terminal disclaimer. Since this is not the only rejection remaining the rejection is herein maintained.

Claims 58 and 62-90 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 and 41-46 of copending Application No. 11/793,473, for reasons of record and stated above.

11. The applicants' amendments and arguments are sufficient to overcome the obviousness-type double patenting rejection labeled paragraph 13) in the last office action, which is hereby **withdrawn**.

12. The applicants' amendments and arguments are sufficient to overcome the obviousness-type double patenting rejection labeled paragraph 14) in the last office action, which is hereby **withdrawn**.

13. With regards to the provisional obviousness-type double patenting rejection of claims 42-65 over copending Application No. 11/599,050 labeled paragraph 15) in the last office action, the applicants' requested that this rejection be held in abeyance at this time.

Claims 58 and 62-90 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of of copending Application No. 11/599,050, for reasons of record and stated above.

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14. The applicants' amendments and arguments are sufficient to overcome the obviousness-type double patenting rejection labeled paragraph 16) in the last office action, which is hereby **withdrawn**.

15. The applicants' amendments and arguments are sufficient to overcome the obviousness type double patenting rejection labeled paragraph 17) in the last office action, which is hereby **withdrawn**.

16. The applicants' amendments and arguments are sufficient to overcome the obviousness type double patenting rejection labeled paragraph 18) in the last office action, which is hereby **withdrawn**.

In view of the amendment dated November 17, 2010, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 67 and 72-90 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for salt forms, does not reasonably provide enablement for solvates and hydrates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claim is drawn to solvates and hydrates. But the numerous examples presented all failed to produce a solvate and

hydrate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 “The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. Hence, applicants must show that solvates and hydrates can be made, or limit the claims accordingly.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624